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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/581,361	06/02/2006	Hiroshi Fujita	053-466-0448	3634
22428 7590 11/14/2008 FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			EXAMINER AFREMOVA, VERA	
			ART UNIT 1657	PAPER NUMBER
			MAIL DATE 11/14/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/581,361

Applicant(s)

FUJITA ET AL.

Examiner

Vera Afremova

Art Unit

1657

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 01 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO/SI/02)
Paper No(s)/Mail Date 6/02/06;3/09/07;6/08/07
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Election/Restrictions

Applicant's election without traverse of the Group I, claims 1-6, in the reply filed on 7/01/2008 is acknowledged.

Claims 7-9 were canceled by applicants.

Claims 1-6 are pending and under examination.

Claim Rejections - 35 USC § 112

Claim 1-6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 is rendered indefinite by the phrase "specifically labeling" with fluorescence. The "specific" meaning of the intended protocol is uncertain as claimed beyond the use of fluorescence.

Claim 5 appears to lack antecedent basis for "the evaluation" step in claim 1 since there is only "detecting" step and evaluation is an intended effect as claimed.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

- (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.
- (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 2 and 5 are rejected under 35 U.S.C. 102 (a or b) as being anticipated by Ruetsch et al. (IDS reference; J. Cosmet. Sci., July/August 2003, 54:379-394).

Claims are directed to a method for evaluating hair damage comprising “specifically labeling” the carbonyl group of an oxidized protein in hair with fluorescence, and detecting the fluorescence. Some claims are further drawn to the hair damage being caused by perm treatment, bleach treatment, treatment with an oxidative hair dye, combing, heat treatment, exposure to UV, and exposure to hypochlorous acid or combination thereof. Some claims are further drawn to detecting fluorescence under a fluorescence microscope.

Ruetsch et al. discloses a method for evaluating hair damage that is based on detection of a fluorescent substance diffused into damaged hair fibers wherein the hair fibers are damaged by photo oxidation, UV, bleaching or perm treatment (page 381). The detection of the fluorescence is conducted under a fluorescence microscope and/or by eye. Ruetsch et al clearly teaches that hair damage affects the structure of hair protein or keratin, that the hair damage results in formation of carbonyl groups and that the overall damaging effect leads to the increased swelling of hair fibers and, thus, to the improved fluorescent substance diffusion (par. bridging page 379-380). Therefore, the cited method comprises step of “specifically labeling” the carbonyl group of an oxidized protein in hair with fluorescence and step of detecting the fluorescence within broad and generic meaning of the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person

having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1-6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ruetsch et al. (IDS reference; J. Cosmet. Sci., July/August 2003, 54:379-394), Hirao et al. (IDS reference; Free Radical Biology and Medicine, 2003, p. S104, Vol. 35, Suppl. 1), Chaudhuri et al. (IDS reference; Free Radical Biology and Medicine, 2003, p. S102, Vol. 35, Suppl. 1) and US 5,302,371 (Lamb et al).

Claims are directed to a method for evaluating hair damage comprising “specifically labeling” the carbonyl group of an oxidized protein in hair with fluorescence, and detecting the fluorescence. Some claims are further drawn to the hair damage being caused by perm treatment, bleach treatment, treatment with an oxidative hair dye, combing, heat treatment, exposure to UV, and exposure to hypochlorous acid or combination thereof. Some claims are further drawn to the use of a hydrazine-group-containing fluorescent substance for reacting with carbonyl group of the oxidized protein in hair for evaluating hair damage. Some claims are further drawn to the use of the hydrazine-group-containing fluorescent substance that is fluorescein-5-thiosemicarbazide or dansylhydrazine. Some claims are further drawn to detecting fluorescence under a fluorescence microscope or by eye.

Ruetsch et al. discloses a method for evaluating hair damage that is based on detection of a fluorescent substance diffused into damaged hair fibers wherein the hair fibers are damaged by photo oxidation, UV, bleaching or perm treatment (page 381). The detection of the fluorescence is conducted under a fluorescence microscope and/or by eye. The reference by Ruetsch et al clearly recognizes the increased formation of carbonyl groups in damaged structure of hair protein or keratin. But the cited method is based on detection of increased fluorescent dye

diffusion as result of overall oxidative damaging effects on hair protein or keratin (par. bridging page 379-380).

However, the reference by Hirao et al. teaches (entire abstract) the use of labeled hydrazine derivatives for detection of carbonyl groups as oxidized targets in keratin exposed to oxidative stress via sunlight, peroxidation, etc. The labeled hydrazine derivatives as disclosed by the reference by Hirao et al are generic. However, the reference by Chaudhuri et al. teaches (entire abstract) the use of a specific compound such as fluorescein-5-thiosemicarbazide for detection of carbonyl groups in various animal tissues and US 5,302,371 (Lamb et al) teaches the use of a specific compound such as dansylhydrazine as fluorescent labeling reagent of proteins in hair application (entire document including col.4, lines 20-45).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to use fluorescence labeled hydrazine-containing compounds such as fluorescein-5-thiosemicarbazide or dansylhydrazine for detection of carbonyl groups in hair keratin with a reasonable expectation of success in evaluating hair damage because the prior art teaches and/or recognizes formation of carbonyl groups in hair keratin damaged by oxidation and because labeled hydrazine derivatives have been used for detection of protein carbonyl groups as adequately taught by the cited references. Thus, the claimed invention as a whole was clearly *prima facie* obvious, especially in the absence of evidence to the contrary.

The claimed subject matter fails to patentably distinguish over the state art as represented by the cited references. Therefore, the claims are properly rejected under 35 USC § 103.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Vera Afremova whose telephone number is (571) 272-0914. The examiner can normally be reached from Monday to Friday from 9.30 am to 6.00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon P. Weber, can be reached at (571) 272-0925.

The fax phone number for the TC 1600 where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology center 1600, telephone number is (571) 272-1600.

Vera Afremova

AU 1657

November 6, 2008

VERA AFREMOVA

PRIMARY EXAMINER

/Vera Afremova/
Primary Examiner, Art Unit 1657